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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,492	12/27/2001	John Kung	JBP0577	9932

27777 7590 12/18/2002
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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,492

Applicant(s)

KUNG ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-14 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-14 and 16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

- I. Claims 1-6, 8-14 and 16-23, drawn to a composition containing oil-soluble and/or water soluble oxygen-labile species and stabilizer compounds, and to a method of stabilizing composition containing oil-soluble and/or water soluble oxygen-labile species using thio-containing compounds or glycoprotein, classified in class 514, subclasses 8 and 251; class 436, subclass 8.

Applicant is required to select one type of stabilizer compounds (thio-containing compound or glycoprotein) in claim 1 or claim 16 because each type of stabilizer compounds are different chemical entities, have different chemical and physical properties, and produce different effects, thus they are patentably distinct. This is not species election.

2. The inventions are distinct, each from the other because of the following reasons:

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the recognized divergent subject matter, and because Inventions require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Andrea Colby on December 4, 2002, a provisional election was made with traverse to prosecute the invention of Group I, claims 1, 3-6, 8-14 and 16, the composition containing glycoprotein as stabilizer compound. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2 and 17-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

3. Claims 1 and 16 are objected to because the claim contains non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-6, 8-14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1, 3-6 and 8-14 are indefinite because of the use of the term "and/or". The term "and/or" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and".

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Claims 3-6, 8-14 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

6. Claims 5, 6, 8-10, 12 and 13 are indefinite because of the use of the term “derivatives”.

The term “derivatives” renders the claim indefinite, it is unclear what compounds are as to “derivatives” and how different the derivative is as compared to the parent compound.

7. Claim 5 is indefinite because of the use of the term “vitamin K tocotrienol”. The term “vitamin K tocotrienol” renders the claim indefinite, it is unclear what “vitamin K tocotrienol” is.

8. Claim 16 is indefinite because of the use of the term “combinations thereof” or “water-soluble oxygen-labile species one or more stabilizer compounds”. The term “combinations thereof” or “water-soluble oxygen-labile species one or more stabilizer compounds” renders the claim indefinite, it is unclear what oxygen-labile species and how many water-soluble and oil-soluble oxygen-labile species are included in the combination, and what the term “water-soluble oxygen-labile species one or more stabilizer compounds” means.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 5, 6, 9 and 12-14 are rejected under 35 U.S.C. 102(b) as anticipated by Jenness (Seminars in Perinatology 3, 225-239 (1972)).

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Jenness discloses the composition of human milk including lactoferrin (Table 4), fatty acids (Table 6) and various vitamins such as vitamin E (α -tocopherol), ascorbic acid, niacin, thiamin, riboflavin, pantothenic acid and folic acid (Table 9; claims 1, 3, 5, 6, 9, 12, 13 and 14).

10. Claims 1, 3, 5, 6, 9, 12-14 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by Gallery *et al.* (US Patent 5,607,681, March 1997).

Gallery *et al.* discloses an antimicrobial composition of iodide and thiocyanate anions, an oxidoreductase enzyme such as glucose oxidase and its substrate, D-glucose (column 1, lines 46-55), and the composition may further comprise lactoferrin and antioxidants such as α -tocopherol and esters thereof, ascorbic acid, salts and esters thereof, flavenoid-containing materials, and mixtures thereof (column 3, lines 29-43; claims 1, 3, 5, 6, 9, 12-14 and 16).

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Chih-Min Kam, Ph. D.
Patent Examiner

CMK

December 4, 2002

Christopher S. F. Low
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SUPERVISORY PATENT EXAMINER
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